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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,857	04/06/2006	Fritz Blatter	2006-0167A	5499
513 7590 08/27/2009 WENDEROTH, LIND & PONACK, L.L.P. 1030 15th Street, N.W., Suite 400 East Washington, DC 20005-1503				
EXAMINER				
HITE-SHEW, FELISA CARLA				
ART UNIT		PAPER NUMBER		
1792				
MAIL DATE		DELIVERY MODE		
08/27/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/574,857

**Applicant(s)**

BLATTER ET AL.

**Examiner**

Felisa C. Hiteshew

**Art Unit**

1792

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed 5/27/2009 have been fully considered but they are not persuasive. The rejections under 35 USC 112, 2<sup>nd</sup> paragraph and 35 USC 102(b) has been maintained..

The applicants' attempt at clarifying the terminology as "... a substantially amorphous form may contain up to 20% by weight, particularly preferably only up to 2% by weight of crystalline phases and may mean a mesomorphic form". is very broad in scope.

The abstract as submitted has been reviewed and considered. Therefore, the objection to the abstract is withdrawn.

### ***Claim Rejections - 35 USC § 112***

a. Claims 1, 3, 7 -10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the terminology "...only substantially amorphous form..." is being considered vague and indefinite.

In claim 9, the terminology "...only substantially amorphous form..." is being considered vague and indefinite. The Term generally or substantially cannot be used to negate the term which they modify. *Arvin Industries v. Berns Air King Corp.* 188 USPQ 49 (CCPA 1975).

Claims 1, 3 and 7-10 are still considered broad and indefinite. The examiner has carefully reviewed the specification on page 6, 2nd paragraph. The organic compounds include nitrogen bases and organic acids (i.e. carboxylic acid, sulphonic acid or phosphonic acid). The terminology organic compound does not further limit the claimed invention and is still being considered too broad and vague in definition.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO 03/026797 A2, WO 01/51919 A2, WO 02/052919 A2 and the article entitled "Polymorphism-integrated approach from high-throughput screening to crystallization optimization", JOURNAL OF THERMAL ANALYSIS AND CALORIMETRY, Hilfecker, et al.

WO 03/026797 A2, WO 01/51919 A2, WO 02/052919 A2 and Hilfecker, et al all disclose methods for the generation and detection of crystallizing compounds using arrays of vessels (e.g. micro-titre plates) so that high-throughput screening of different parameters may be assessed and the properties of the resulting solid forms may be analyzed in parallel. The prior art references, cited supra, disclose the use of solvents and amorphous forms (e.g. saturated or supersaturated solutions) among the possible

starting solutions for the solid form. After the crystallization is carried out, the array plate comprises a variety of solid-forms which may then be identified and related to the comprising flow-through seals connected to one or more gas sources or vacuum pumps. WO 03/026797 A2, WO 01/51919 A2, WO 02/052919 A2 and Hilfefer, et al also disclose an apparatus comprising arrays of vessels, means for heating/cooling, stirring and means for detecting (e.g. Raman spectroscopy) the resulting solid forms.

WO 00/60345 A1 discloses methods of screening and analyzing crystal growth conditions. The method comprises the use of a micro-array of vessels comprising heating/cooling means as well as means for stirring the samples. Once the crystallization has been carried out the array of solid-forms (e.g. amorphous) are analyzed using microscopy. It would have been obvious to one of ordinary skill in the art to optimize and modify the disclosed methods for the generation and detection of crystallizing compounds using arrays of vessels to encompass the method and apparatus teachings of the instant invention.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Felisa Hiteshew whose telephone number is (571) 272-1463. The examiner can normally be reached on Mondays through Thursday from 5:30 AM to 4:00 PM with Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Mikhail Kornakov, can be reached on (571) 272-1414. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-1463.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system; contact the Electronic Business Center (EBC) at 866- 217-9197 (toll-free).

/Felisa C. Hiteshew/  
Primary Examiner, Art Unit 1792